IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

HEALTH CHOICE GROUP, LLC, on behalf of The United States of America, et al.,

Plaintiff/Relator,

v.

BAYER CORPORATION, et al.,

Defendants.

Civil Action No. 5:17-cv-126-RWS-CMC

FILED UNDER SEAL

DEFENDANTS' MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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Defendants Bayer Corporation ("Bayer), AmerisourceBergen Corporation ("Amerisource"), and Lash Group ("Lash") (collectively "Defendants") respectfully move to dismiss the Second Amended Complaint ("SAC") with prejudice pursuant to Fed. R. Civ. P. 9(b).

STATEMENT OF THE ISSUES

1. Whether the SAC, like the First Amended Complaint ("FAC"), fails to meet the heightened pleading requirements of Rule 9(b) for all counts.

INTRODUCTION

In the Report & Recommendation ("R&R"), to which Relator did not object, the Court articulated the standard Relator must meet to satisfy Rule 9(b). Rule 9(b)'s heightened pleading standard requires Relator to sufficiently plead the "who, what, when, where, and how" of the alleged acts and "reliable indicia" that Defendants' conduct actually caused the submission of false claims. *See* R&R at 92. To meet this standard, Relator must at least "identify a single doctor who eliminated staff positions (or who such staff are) or otherwise actually received 'substantial value' as a result of the free nurse or reimbursement support services provided." R&R at 82. Despite this being Relator's third bite at the apple, the SAC still does not satisfy Rule 9(b).

Rather than plead fraud with particularity, the SAC adds no meaningful new details regarding specific prescribers who eliminated staff positions or otherwise received "substantial independent value" from Defendants' programs, when the alleged Anti-Kickback Statute ("AKS") violations occurred, and how the alleged AKS violations *caused* the submission of even one false claim. Indeed, Relator fails to allege with particularity that any false claims were actually submitted by any particular doctors, or to link any such false claims to the alleged kickback schemes. Relator cannot proceed without such particularized allegations.

The Court's dismissal should be with prejudice. Following the Court's issuance of the R&R, Relator has used "market research" interviews of Defendants' former employees and Defendants' discovery material in an attempt to plead its claims with particularity. Both of these tactics are improper and demonstrate the futility of permitting further amendment.

BACKGROUND

Judge Craven issued the R&R on Defendants' Motion to Dismiss Relators' FAC on June 29, 2018, Dkt. 91, which was adopted in full by the Court. Dkt. 98. The order dismissed Relator Jamie Green from the litigation and granted Defendants' motion to dismiss on Rule 9(b) grounds without prejudice. *Id.* On August 15, 2018, Relator Health Choice Group, LLC ("HCG"), filed the SAC. Dkt. 102.

Similar to the FAC, Relator's SAC alleges each Defendant caused the submission of false claims for reimbursement of Betaseron, Adempas, Nexavar, and Stivarga[1] (collectively, the "Covered Products"). These alleged false claims relate to nurse education and reimbursement support services and alleged "white coat marketing." Relator claims that these programs constituted illegal remuneration under the AKS, and thus Defendants caused the submission of false claims for reimbursement of the Covered Products, in violation of the FCA.

Relator has supplemented the SAC with new allegations in an attempt to satisfy Rule 9(b). As described further below, these new allegations neither address the "what," "how," or "when" of the alleged "schemes," nor explain how Defendants' conduct actually caused the submission of false claims. For instance, Relator has failed to identify a single prescriber who eliminated staff positions due to Defendants' nurse education or reimbursement support services. Instead, the new allegations in the SAC are improperly based on information obtained through Defendants'

[1] Relator added Stivarga to the Second Amended Complaint.

materials produced in discovery and interviews of former employees under the guise of unbiased "market research."

While the new allegations in the SAC are insufficient to meet the requirements of Rule 9(b), they should not even be considered by the Court. Relator is not permitted to supplement its deficient fraud claims with information learned from discovery. Yet approximately 70 paragraphs in the SAC are based entirely on Defendants' discovery materials.

In addition, it has become increasingly clear that Relator's allegations—in the FAC and the SAC—are based on misleading interview tactics. For instance, Joseph Locastro, Relator's employee and a licensed attorney in the state of Pennsylvania, conducted misleading interviews of a number of Defendants' former employees. Mr. Locastro failed to disclose to interviewees that: (1) he is an attorney; (2) he was collecting information for potential use in a lawsuit; or (3) the organization for which he worked was created to pursue False Claims Act cases. Instead, he told interviewees that his organization had "no bias one way or the other about the [healthcare] industry," and that it hoped "to have a positive influence on how nurse educators are used by pharmaceutical companies."

STANDARD

"Claims brought under the FCA are fraud claims that must also comply with the supplemental pleading requirements of Rule 9(b)." *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 (5th Cir. 2013) (quoting Fed. R. Civ. P. 9(b)). As this Court has previously recognized, "Relator[] must plead [its] FCA claim[s] with particularity, including each element of the alleged AKS violations." R&R at 66. In the Fifth Circuit, a complaint alleging FCA claims must describe "the 'who, what, when, where, and how'" of the alleged fraud to satisfy Rule 9(b). *Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. 2003) (internal citation omitted). A complaint must also provide "reliable indicia" that false claims were actually

submitted "as a result of" the alleged scheme. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009). Courts in the Fifth Circuit apply Rule 9(b) to FCA complaints "with 'bite'" and "without apology." *U.S. ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 903 F. Supp. 2d 473, 484 (E.D. Tex. 2011) (internal citation omitted), *rev'd on other grounds*, 727 F.3d 343 (5th Cir. 2013) (quoting *Grubbs*, 565 F.3d at 185).

ARGUMENT

I. Relator's FCA Claims (Counts 1-3) Should Be Dismissed Pursuant To Rule 9(b) Because Relators Have Not Pled Fraud With Particularity.

Relator's claims are fatally flawed because they fail to provide the "who, what, when, where, and how of the alleged fraud" or "reliable indicia" that actual claims were submitted to government health programs "as a result of" the alleged fraud. R&R at 82.

A. The SAC Lacks Sufficient Allegations Regarding the Who, What, When, and How of the Alleged Kickback Schemes.

To satisfy Rule 9(b), Relator must: (1) identify specific prescribers who eliminated staff positions or otherwise received substantial independent value due to the nurse education or reimbursement support services, *see* R&R at 82; (2) identify specific prescribers who were the targets of white coat marketing, *see id.* at 88; (3) demonstrate how the nurse education and reimbursement support services provided "substantial independent value" to prescribers, *see id.* at 80–82; and (4) allege with sufficient detail when the alleged schemes took place, *see id.* at 83. The SAC fails to meet any of these requirements.

1. Insufficient Allegations Regarding the "What" and "How"

This Court found that the FAC failed to satisfy Rule 9(b) because Relator (1) did "not identify a single doctor who eliminated staff positions (or who such staff are) or otherwise actually received 'substantial value' as a result of the free nurse or reimbursement support services provided," and (2) "fail[ed] to explain which defendant undertook what alleged act, when those

acts occurred and with whom, and . . . how those alleged acts caused a false claim that was submitted to the Government." R&R at 82. The SAC is similarly deficient. It does not identify a single doctor who eliminated staff positions or otherwise actually received "substantial value" as a result of the alleged nurse education or reimbursement support services. *Id.*

Guidance from the Office of Inspector General states that product support services that are "specifically tied to support of the purchased product" standing alone do not implicate the AKS, but that such services may constitute illegal remuneration if those services provide some "substantial independent value to the purchaser." Office of Inspector General, U.S. Department of Health and Human Services, Compliance Program Guide for Pharmaceutical Manufacturers at 19–20 (2003). As this Court has explained previously, Relator must "describe with sufficient specificity how [Defendants'] free services crossed the line separating permissible product support from illegal remuneration with independent value to the purchaser." R&R at 80 (quoting *U.S. ex rel. Forney* v. *Medtronic, Inc.*, No. CV 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017)). Additionally, Relator must "demonstrate that any independent value to the purchaser was substantial." *Id.* (quoting *Forney*, 2017 WL 2653568, at *4). "Simply stating that the services generally benefited [Defendants'] bottom lines or that physicians used [Defendants'] services in lieu of having to pay for their own employees, is not sufficiently specific to meet the pleading requirements of Rule 9(b) without alleging how those services substantially benefited customers' bottom lines." *Forney*, 2017 WL 2653568, at *4.

Nurse Education Services. Relator's entire case rests on the dubious proposition that Defendants' allegedly illegal "schemes" allowed physicians to eliminate staff positions. However, the SAC *does not identify a single physician who actually eliminated staff positions* as a result of Defendants' programs. In a half-hearted attempt to show that these support services affected

physicians' hiring decisions, Relator relies upon the alleged statements of Jessica Larsen, a patient access coordinator at the Schapiro Center, who supposedly "confirmed" Relator's assertion that if Beta Nurse Ann Crawford "had not performed these services, Schapiro Prescribers, such as Dr. Jonathan Calkwood, would have had to hire his own staff person to take those calls or make those home visits." SAC ¶ 122. This single allegation is deeply flawed and, more importantly, insufficient under Rule 9(b) to support a claim that Defendants engaged in a years-long scheme to defraud the Government, as Relator alleges. *See, e.g., U.S. ex rel. Woodard v. DaVita, Inc.*, No. 1:05-CV-227, 2011 WL 13196556, at *12 (E.D. Tex. May 9, 2011) ("Rule 9(b) simply does not allow [Relator] to rest his pleading of a years-long scheme . . . on two allegations, each of which is itself significantly lacking in supporting facts."). Relator does not allege that the Schapiro Prescribers *actually eliminated* staff positions as a result of the nurse education services. Rather, Relator alleges that absent Ms. Crawford, they would have had to *hire* staff to perform the services she provided. SAC ¶ 122. However, Ms. Crawford stopped interacting with the Schapiro Center in October 2015, and there is no allegation that additional staff were, in fact, hired to provide the services she offered. Further, there is no allegation that Ms. Crawford assumed the responsibility of any member of the Schapiro Center staff when she began educating its patients.

Similarly, the SAC does not identify a single Prescriber or staff member who received "substantial independent value" from the nurse education services. The SAC notes that Ms. Crawford would "help manage . . . patients so that the office doesn't have to [which] frees up their time to see other patients." SAC ¶ 120. But the SAC fails to identify a specific staff person or prescriber whose time was "freed up," nor does it provide any details regarding the additional patients who were allegedly seen as a result of Ms. Crawford's services. The SAC also alleges that Danielle Minetti provided nurse education services to Dr. Picone, SAC ¶¶ 124–25, Dr. De La

Torre, Dr. DiPaolo, Dr. Tsai, Dr. Jennis, and Dr. Malek, SAC ¶ 131, but makes no attempt to specify how the nurse education services provided them with "substantial independent value."

Rather than provide specifics, the SAC generally asserts that the nurse education services "reduced the time and cost required of Prescribers across the nation . . . to treat chronically ill patients . . . thereby freeing up Prescribers' and their staff's time and resources," and "allowed the Prescribers to see additional patients, thereby increasing the overall profitability of their practices." SAC ¶ 139. Here, as in *Forney*, Relator has simply alleged that the nurse education and reimbursement support services generally benefited Defendants' bottom lines and that physicians used Defendants' services in lieu of having to pay for their own employees. 2017 WL 2653568, at *4. Such general assertions fail to satisfy Rule 9(b) because they do not "demonstrate that any independent value to the purchaser was substantial." *Id.*

Therefore, not only does the SAC lack specificity in alleging that prescribers eliminated staff positions as a result of Defendants' nurse education or reimbursement support services, but it also lacks any allegation that prescribers would have provided these services absent Defendants' programs. This completely undermines Relator's argument that the nurse education or reimbursement support services freed up prescribers' and their staff's time and resources or changed physician staff hiring practices.

Reimbursement Support Services. The SAC fails to identify a single prescriber who even utilized Bayer's reimbursement support services. The SAC contains only one allegation related to a specific prescriber—that Ms. Crawford provided some assistance with insurance "issues" at the Schapiro Center. *See* SAC ¶¶ 122, 228. However, by Relator's own words, Ms. Crawford was employed as a Beta Nurse, not a reimbursement support services representative. *See* SAC ¶ 83. Therefore, any reimbursement support services she allegedly provided were not part of the

reimbursement support services program that Relator alleges constituted a separate scheme to violate the AKS. Although the SAC alleges that Exhibits A–K consist of "specific examples" of Medicare or Medicaid claims "resulting from some of the Prescribers who were targeted with Free Nurse, Support Services, and White Coat Marketing schemes," *see* SAC ¶¶ 265–270, as noted above, the SAC only contains specific allegations regarding five of the 35 prescribers listed in those exhibits (Dr. Calkwood, Dr. DiPaolo, Dr. Tsai, Dr. De La Torre, and Dr. Picone). Moreover, Relator only alleges that those five prescribers received nurse education services, *not* reimbursement support services. Because the SAC fails to identify any prescribers who utilized the reimbursement support services, it has also necessarily failed to prove that anyone received substantial independent value as a result of these services.

White Coat Marketing. Relator alleges that Lash and Ashfield nurse educators were "expected to supplement Bayer's sales force and engage in marketing activities," SAC ¶ 160, which violated "the AKS prohibit[ion] [on] pharmaceutical companies . . . paying non-employees to 'recommend' Bayer drugs to others." SAC ¶ 158. Even if the AKS contained such a categorical prohibition—which it does not—the SAC fails to allege with particularity that the Lash and Ashfield nurse educators "recommended" the medications *because of* any alleged remuneration. Relator claims only that nurse educators were "*in a position* to recommend drugs" to prescribers. SAC ¶ 169 (emphasis added). However, Relator makes no allegations that any of the nurse educators did, in fact, make any prescription recommendations to prescribers. Alleging mere "opportunity and motive" does not reasonably support an inference of action. *See, e.g.*, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("Factual allegations must be enough to raise a right to relief above the speculative level."); *see also Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1205–

06 (11th Cir. 2007) ("Our duty to accept the facts in the complaint as true does not require us to ignore specific factual details of the pleading in favor of general or conclusory allegations.").

The SAC first relies upon the contracts between Bayer and Lash in a flawed effort to allege that nurse educators were engaging in white coat marketing.[2] The documents that Relator cherry-picked from Bayer's discovery actually undermine this claim, however, because they do *not* show that nurse educators were expected to recommend products. Rather, they show that the nurse educators were supposed to provide education services. For example, the Beta Nurse contract between Bayer and Lash states that Beta Nurses "shall partner with Bayer's sales consultants to provide training and education to healthcare providers . . . . Field Nurse participation in patient programs shall attempt to increase compliance with the patient's prescribed Betaseron therapy and increase the overall quality, consistency and effectiveness of the Betaseron patient programs." SAC ¶ 161. The NexConnect contract between Bayer and Lash states that nurse educators for Nexavar and Stivarga were expected to "[a]ddress certain specific questions about Nexavar and provide disease management education and materials about the specific disease process to Customers (all as approved in writing by Bayer)." SAC ¶ 162. Neither of these contracts suggests that nurse educators were expected to recommend Bayer products.

The SAC also relies upon alleged statements by nurse educators. However, these statements do not show that nurse educators recommended products—in fact, they indicate that nurse educators simply provided education services. SAC ¶ 170 (quoting Beta Nurse Russell, who stated, "It was such a big plus for the sales rep to be able to travel with a Beta nurse," but did not

[2] As discussed in Section IV, *infra*, the use of discovery to bolster a claim of fraud violates the law and purpose of Rule 9(b). Without the benefit of Defendants' discovery, Relator would not have been able to take these contracts between Defendants out of context in an effort to make these new, flawed allegations.

claim that she or any other Beta Nurse promoted the drug); SAC ¶ 174 (alleging that sales reps and nurse educators would plan to meet with prescribers together; but no mention of any nurse educator recommending any product); SAC ¶ 173 (Crawford explaining that she wanted to communicate "a lot" and paid "attention to" prescribers who referred patients, but no allegation that she or any other Beta Nurse promoted or recommended Betaseron). Relator further proves this point when it alleges that a sales representative, *himself*, was able to more effectively promote his product when a nurse educator had a relationship with a prescriber, but does not allege that any nurse educator promoted or recommended the drug. SAC ¶ 177 (Nexavar drug representative, stated, "[s]o any time you can have access from a nursing point of view that really helps you with . . . promoting your product in that particular practice").

Because the SAC fails to identify a single prescriber who eliminated staff positions as a result of the free nursing and reimbursement services, does not identify a single prescriber who benefited from the reimbursement services or was the target of white coat marketing, and only makes general allegations as to how the services theoretically provided independent value to prescribers, the SAC fails to meet the pleading requirements of Rule 9(b).[3]

[3] As argued in Defendants' First Motion to Dismiss, Relator's legal premise—that "the AKS prohibits pharmaceutical companies from paying non-employees to 'recommend' Bayer drugs to others," SAC ¶ 158—is simply wrong. The AKS has both statutory and regulatory "safe harbors" expressly permitting pharmaceutical companies to engage non-employees to provide promotional services. *See* 42 U.S.C. § 1320a-7b(b)(3)(C); 42 C.F.R. § 1001.952(d) (listing relevant factors in evaluating "personal services and management contracts" for non-employee agents, including those engaged in promotion). And in direct contrast to Relator's legal conclusion, the OIG's Compliance Program Guidance makes clear that merely paying a third-party contractor to "recommend" a product, without more, is not a violation of the AKS. *See* 68 FR 23731-01, at 23739.

2. Insufficient Allegations Regarding the "When"

Relator also fails to sufficiently identify when the alleged schemes took place. Under Rule 9(b), Relator must "allege at least approximate dates of the alleged fraud in a manner such that they appear to be more than mere speculation or conclusory allegations." *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006). This Court previously found that "Relator['s] timeframe allegations regarding the nurse educator programs Beta Plus ('has been around for at least the last decade' before ending in 2015) and NexConnect ('began at least as far back as 2009' and is still in operation)" failed to "sufficiently identify when the alleged schemes to violate the AKS took place." R&R at 83. The SAC's temporal allegations are similarly inadequate.

Nurse Education Services and White Coat Marketing. Relying on contracts produced in discovery, the SAC alleges that the Nexavar nurse education program was "[a]dministered by Lash: November 2007 – October 2015 and administered by inVentiv Health: October 2015 – current"; the Stivarga nurse education program was "administered by Lash September 2012 – October 2015 and administered by inVentiv Health: October 2015 – current"; and the Betaseron nurse education program has been administered by Lash from "Fall 2009 – current."[4] SAC ¶ 151. Also based on those contracts, Relator alleges that White Coat Marketing occurred during the entire time period that Defendants offered nurse education services. SAC ¶ 198. As noted in the R&R, alleging the timeframes when Bayer contracted with Lash and inVentiv to provide nurse education services for the Covered Products is insufficient to identify "when" the nurse education

[4] As discussed in Section IV, the use of discovery to bolster a claim of fraud violates the law and purpose of Rule 9(b). Without the benefit of Defendants' discovery, Relator would not have been able to make these new allegations.

services violated the AKS or "when" Defendants allegedly engaged in white coat marketing for purposes of Rule 9(b).

Reimbursement Support Services. Relator's allegations about "when" Defendants' reimbursement support services crossed the line into "kickbacks" are even less particularized. Relator alleges that the reimbursement support services have been violating the AKS in unspecified ways for more than 13 years. *See* SAC ¶ 238 (chart noting the product and the time period that reimbursement services have been available: Nexavar = Late 2005–current; Stivarga = September 2012–current; Betaseron = January 2009–current). These are the same generalized, non-particularized allegations made in the FAC, which this Court has already found insufficient. *See* R&R at 83.

By alleging fraud over such expansive time frames, Relator has failed to prove that these allegations are "more than mere speculation or conclusory." *U.S. ex rel. Lam*, 481 F. Supp. 2d. at 688.

3. Insufficient Allegations Regarding The "Who"

Relator also fails to sufficiently identify who was involved in the alleged AKS schemes. The R&R found the FAC insufficient because, among other reasons, it contained "no details regarding . . . who was involved (not a single staffer, patient, or anyone other than, by implication, the anonymous interviewee him- or herself). Further, the Court found that the FAC did not "identify any individuals who were involved in the reimbursement support services scheme," because "the only individuals mentioned are CI-2 or CI-5 and the Prescribers themselves," but by Relator's "own account, 'support staff,' not prescribers, typically perform the administrative function to which the reimbursement services are relevant." R&R at 89.

The SAC attempts to cure these deficiencies by unmasking Relator's CIs, *see* SAC ¶ 83, and naming eight prescribers who allegedly utilized nurse education services. SAC ¶ 116 (Dr.

Randy Schapiro and Dr. Jonathan Calkwood); SAC ¶ 125 (Dr. Mary Picone); SAC ¶ 131 (Dr. De La Torre, Dr. Patrick DiPaolo, Dr. Phillip Tsai, Dr. Andrew Jennis, and Dr. Ashraf Malek). Naming these previously confidential individuals is woefully insufficient. Like the FAC, the SAC still fails to provide details regarding who, apart from the handful of individuals listed above, was involved in the alleged nation-wide, 10-year-plus scheme (not a single staffer, patient, or anyone other than nurse and prescriber have been identified).

Moreover, like the FAC, the SAC does not identify a single prescriber who utilized the free reimbursement services or was the target of white coat marketing. *See* R&R at 89. The SAC implausibly identifies Ms. Larsen, a patient access coordinator at the Schapiro Center, who stated that Beta Nurse Ann Crawford spent 5 hours per week performing reimbursement services. SAC ¶ 122. However, according to Relator's own complaint, she was employed as a Beta Nurse, not a reimbursement support services representative. *See* ¶ 83. Thus, any reimbursement services she provided were not part of the reimbursement support services program that Relator alleges constituted a separate scheme to violate the AKS. Further, although the SAC alleges that SAC Exhibits A–K consist of "specific examples" of Medicare or Medicaid claims "resulting from some of the Prescribers who were targeted with the Free Nurse, Support Services, and White Coat Marketing schemes," *see* SAC ¶¶ 265–70, Relator only makes specific allegations about five of the 35 prescribers listed in those exhibits (Dr. Calkwood, Dr. DiPaolo, Dr. Tsai, Dr. De La Torre, and Dr. Picone). And, as detailed above, the allegations related to those doctors apply only to nurse education services.

Relator also includes lists of individuals employed by Bayer and Lash[5] who were allegedly "involved in developing and administering the Free Nurse Program," SAC ¶ 144, "responsible for designing, approving, and implementing the White Coat Marketing program," SAC ¶ 197, and "involved in the design, approval, and implementation of the Support Services Program," SAC ¶ 237. Although Relator named a number of individuals, these names do nothing to prove the "who" for purposes of Rule 9(b) because these individuals are simply employees of Bayer and Lash, not the nurse educators, support staff, and physicians who were involved in the complained of *quid pro quo* AKS violations. Because Relator's allegations regarding the "who" are conclusory, and are "significantly lacking in supporting facts," Relator has failed to satisfy Rule 9(b). *See Woodard*, 2011 WL 13196556, at *12 ("Rule 9(b) simply does not allow [relator] to rest his pleading of a years-long scheme . . . on two allegations, each of which is itself significantly lacking in supporting facts.").

Relator has not sufficiently identified who was involved in the alleged AKS schemes, and thus has failed to meet 9(b)'s requirements.

B. The SAC Contains No Detail Regarding The Submission Of False Claims, Much Less "Reliable Indicia" That False Claims Actually Were Submitted As A Result Of The Alleged Schemes.

As with the FAC, Relator fails to sufficiently allege the submission of a single false claim, or to link any such false claim(s) to the three programs. This failure is a separate basis for dismissal. The *sine qua non* of an FCA claim is the submission of an actual false claim for payment to the Government. *U. S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 813 (E.D. Tex. 2008). The FCA "attaches liability, not to the underlying fraudulent activity . . . but to

[5] Relator copied-and-pasted these names from Defendants' Initial Disclosures in this case—once again wrongfully trying to use discovery to bolster a deficient pleading. *See infra* at Section IV (citing cases holding that discovery cannot be used to satisfy Rule 9(b)).

the 'claim for payment.'" *U.S. ex rel. Patton v. Shaw Servs., LLC*, 418 F. App'x 366, 369 (5th Cir. 2011) (citation omitted). Even if Relator had sufficiently pled the existence of such "claims for payment," it must also allege with particularity that Defendants' challenged conduct caused them to be submitted. *U.S. ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 372 (5th Cir. 2017).

The SAC fares no better than the previously dismissed FAC because its allegations fail to allege with particularity that Defendants' conduct actually caused the submission of false claims. *See* R&R at 101–03. The Court found the FAC insufficient because Relator (1) did "not allege any specific instance in which one of the Covered Products was prescribed or a claim was submitted *as a result of* the three schemes," and (2) did "not make the necessary connection that any such claim was then submitted through [a government insurance program]." *Id.* at 102 (emphasis added). The same is true of the SAC.

The SAC does not allege any specific instance in which one of the Covered Products was prescribed or a claim was submitted "as a result of" the three "schemes." Nor does it make the necessary connection that any such claim was then submitted to a Government healthcare program. *See U.S. ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("[I]t would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe [defendant's] drugs to Medicaid patients."). The majority of new allegations related to the submission of false claims come from two people. *See* SAC ¶¶ 123–27, 131, 136, 228. Jessica Larsen and Danielle Minetti name eight prescribers who Relator alleges received nurse education services. *See id.* The SAC makes no new allegations about the submission of claims caused by white coat marketing and reimbursement support services.

The SAC focuses on a few nurses' access to patients, but again fails to "tie" the allegations "together into particularized charges about specific fraudulent claims for payment." *U.S. ex rel.*

Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 15 (1st Cir. 2016); *see also* R&R at 102–03. Relator fails to allege that any nurse's actions affected any doctor's prescribing decision, much less actually resulted in the submission of a false claim. Like the FAC, the SAC contains no allegations that one of the Covered Products was ever prescribed as a result of either the nurse educator or reimbursement support services programs. Instead, in an effort to save its insufficient claims, Relator alleges, without more detail, that nurse education services were performed. For example, the SAC says that Danielle Minetti "performed free nursing services for Dr. Mary Picone in Teanack, New Jersey," SAC ¶ 125. Yet Relator does not identify a single instance in which Dr. Picone prescribed one of the Medicines *because of* Ms. Minetti's services. Likewise, the SAC contains Jessica Larsen's statement that the Schapiro center was "going to be more apt to use, [] Betaseron, because we have such a wonderful person [Ms. Crawford] helping to facilitate that drug." SAC ¶ 123. This does not allege with particularity that one of the Covered Products was ever prescribed or a claim was submitted as a result of the alleged scheme. Ms. Larsen was not a prescriber, and Relator does not allege a single instance when a Schapiro Center doctor prescribed Betaseron *as a result of* Ms. Crawford's services. Because Relator again alleges only the presence of nurse educators without explaining how their presence *resulted in* false claims, *see* R&R at 102–03 ("Relators allege 'nurse educators gained access to Prescribers,' (citation omitted), but do not sufficiently explain how this access resulted in false claims that were then submitted to the Government."), the allegations fail to satisfy Rule 9(b).

Relator also attempts to convince the Court that it has sufficiently alleged the submission of false claims by attaching lists of Medicare and Medicaid claims for prescriptions of Betaseron,

Nexavar, Stivarga, and Adempas. *See* SAC, Exhibits A–K.[6] However, these claim lists do not establish that any claims were *false*. SAC Exhibits A–K are lists of insurance claims from prescribers who Relator does not and cannot connect to the underlying conduct it alleges.

Relator's description of the contents of SAC Exhibits A–K reveals the exhibits' deficiencies. Relator alleges that the exhibits consist of "specific examples" of Medicare or Medicaid claims "resulting from some of the Prescribers who were *targeted* with the Free Nurse, Support Services, and White Coat Marketing schemes." *See* SAC ¶¶ 265–70 (emphasis added). Relator does not even allege that 30 of the 35 prescribers listed in SAC Exhibits A–K ever even received nurse education or reimbursement support services, or were visited by nurse educators at any point, much less in connection with the prescriptions identified in the exhibits. And, as detailed above, the allegations related to the remaining five prescribers state only that they received nurse education services. Similarly, the SAC contains no specific allegation that any of the 35 prescribers named in SAC Exhibits A–K prescribed one of the Covered Products *as a result of* the alleged schemes.[7] Relator's failure to name a single doctor from SAC Exhibits A–K who

[6] Other than SAC Exhibits A–K, the only data presented to support Relator's argument that false claims were actually submitted are the previously-rejected charts of Medicare and Medicaid claims by state for each of the Covered Products. *See* SAC ¶¶ 282, 284, 286, 288, 290–96; *see also* R&R at 103 ("[T]he charts of publicly available information regarding Medicare and Medicaid reimbursements do not remedy the disconnect between the alleged underlying conduct and any actual false claims for reimbursement. The charts show collective government reimbursement figures without any indication those statewide payments had anything to do with any alleged kickback from Defendants.").

[7] In fact, the claims data provided by Relator undermines the argument that the presence of Beta Nurses impacted prescriptions of the Medicines. For example, the SAC alleges that Ann Crawford served as a Beta Nurse for the patients of Jonathan Calkwood, *see* SAC ¶ 116, until October 2015, *see* SAC ¶ 82. The claims data provided by Relator in Exhibit A links Dr. Calkwood to 116 Betaseron claims from the first date for which there is data, October 3, 2013 to September 29, 2015, the approximate date of Ann Crawford's departure. In the two year period after Ann Crawford worked for Dr. Calkwood, Dr. Calkwood prescribed Betaseron 109 times. The fact that Dr. Calkwood wrote nearly the same number of prescriptions when he received Ann Crawford's

prescribed one of the Covered Products *as a result of* the alleged schemes compels dismissal. *See* R&R at 102.

Finally, the SAC fails to allege the details of the alleged schemes with particularity, *see supra* I.A., and contains no details demonstrating that Defendants intended to cause the submission of false claims.[8] The SAC, like the FAC, "lacks the level of detail required, even under a 'reliable indicia' standard, for pleading the submission of false claims." *See* R&R at 103. The lack of sufficient detail distinguishes this case from cases like *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.* (cited in the R&R), where the complaint was deemed barely adequate when the relator "allege[d] [] the who, what, where and when of the allegedly false or fraudulent representation" and "also alleged facts with respect to the medical providers he identifie[d] that support[ed] his claim that [the defendant] *intended* to cause submission of false claims." *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) (internal quotation marks omitted). Additionally, Relator's "investigation," SAC ¶ 82, which included interviews of former employees and a person from a medical facility who had proximity to prescribers and patients, distinguishes this case from one where Rule 9(b)'s requirements might be relaxed because the facts are

services as when he did not undermines Plaintiff's argument that Ms. Crawford's services caused the submission of false claims.

[8] Relator also impermissibly attaches internal, confidential documents that show that Medicare and Medicaid patients were prescribed the Covered Products, but as with the publically available data attached to the FAC, these presentations are insufficient to demonstrate that an actual false claim was made because Relator does not and cannot link these prescriptions to the underlying conduct alleged. *See United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-0604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016) ("The mere fact 93% of Defendants' patients are Medicare patients is not sufficient to show Defendants submitted claims that falsely certified compliance with the AKS"); *see also U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 58 (1st Cir. 2017) (holding that "aggregate [information] reflecting the amount of money expended by Medicaid" on off-label prescriptions was "insufficient" because it did not show "an actual false claim made to the [G]overnment.").

"peculiarly within the defendants' control." *See* R&R at 98 (quoting *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 355 (D. Mass. 2011)). Relator's case is entirely based on interviews of people who would be in a position to identify with particularity any "false" claims that were submitted. This makes Relator's inability to identify the details of the scheme or a single false claim even more egregious.

Relator's scant new allegations and inability to connect the claims in SAC Exhibits A–K to the alleged AKS schemes prevents it from meeting the standard previously set by the Court and compels dismissal under Rule 9.

II. The Conspiracy Claim (Count 3) Should Be Dismissed Because the FAC Fails to Allege the Essential Elements of a Conspiracy Claim.

To state an FCA conspiracy claim, Relators must show (1) the existence of an unlawful agreement between Defendants to get a false or fraudulent claim allowed or paid by a government payor and (2) at least one act performed in furtherance of that agreement. *U.S. ex rel. Farmer v. City of Hous.*, 523 F.3d 333, 343 (5th Cir. 2008). "As part of that showing, the plaintiff must demonstrate that the defendants shared a specific intent to defraud the government." *U.S. ex rel. Ramsey-Ledesma v. Censeo Health, LLC*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *11 (N.D. Tex. Sept. 30, 2016). "The particularity requirements of Rule 9(b) apply to the [FCA's] conspiracy provision with equal force as to its 'presentment' and 'record' provisions." *U.S. ex rel. Hartwig v. Medtronic, Inc.*, No. 3:11CV413-CWR-LRA, 2014 WL 1324339, at *5 (S.D. Miss. Mar. 31, 2014) (quoting *Grubbs*, 565 F.3d at 193). Therefore, in order to move forward on its conspiracy claim, the relator must "plead with particularity the conspiracy as well as the overt acts . . . taken in furtherance of the conspiracy." *Id.* (citation omitted).

As this Court previously held, the FAC failed to plead conspiracy with particularity because it provided no "factual basis to determine the roles of each defendant in any agreement or

each defendant's specific intent to defraud." R&R at 109. The SAC is equally deficient. As an initial matter, Relator's conspiracy claim fails because it has not pled any underlying FCA violation. *U.S. ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 509 (S.D. Tex. 2003), *aff'd*, 111 F. App'x 296 (5th Cir. 2004) (conspiracy claim failed as a matter of law because underlying FCA claims were dismissed).

In addition, the SAC fails to allege an actual agreement to violate the AKS or present false claims to a government insurance program. As this Court has previously recognized, such allegations are necessary to meet the Rule 9(b) standard. R&R at 109–10.[9] *See Ramsey-Ledesma*, 2016 WL 5661644, at *12 (Relator failed to plead "any specific facts that would support the inference that Humana or Tufts had an actual agreement with Censeo or Altegra to create false records or present false claims to CMS.").

Relator vaguely asserts that "Bayer conspired with Amerisource and Lash, physicians, and other health care professionals" to violate the FCA. SAC ¶ 332. But nowhere does Relator allege—let alone with particularity—that Bayer had any unlawful agreement to conspire with Amerisource and Lash, or with other health care professionals to defraud the Government. The fact that Bayer contracted with Amerisource and Lash to provide nurse education and reimbursement support services does not support an inference that Bayer and Amerisource and/or Lash had an agreement to "offer or pay kickbacks in exchange for, or to induce [prescribers] to purchase, order, or recommend the purchasing or ordering of Covered Products." SAC ¶ 332.

[9] Even if the SAC could be construed as alleging a conspiracy between Amerisource and its subsidiary Lash, the claim would be barred for the additional reason that a corporation cannot conspire with its own subsidiary. *U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 856 (S.D. Tex. 2003) (citing *Deauville Corp. v. Federated Dept. Stores, Inc.*, 756 F.2d 1183, 1192 (5th Cir. 1985)) ("[I]t is a matter of law that a parent corporation cannot conspire with its own subsidiary."), *aff'd*, 384 F.3d 168 (5th Cir. 2004).

Indeed, this Court and others have found conspiracy claims with more specific allegations than exist here to be legally deficient. *See, e.g.*, *U.S. ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 208 (E.D. Tex. 1998) (dismissing conspiracy claims under Rule 9(b) despite allegations of "a pattern of . . . coordinated schemes," of misrepresentations through "buy/sell agreements between [defendants]," that defendants "knowingly employed these schemes in a calculated and concerted effort to cheat the United States," that they "entered into [agreements] with each other" to make misrepresentations, and that "[e]very Defendant performed an overt act in furtherance of the conspiracy").

III. The State Law Counts (Counts 4-32) Should Be Dismissed For the Same Reasons as the FCA Claims.

In the R&R, the Court held that state FCA claims are subject to the pleading requirements of Rule 9(b). R&R at 112. "To meet this heightened pleading standard, Relators must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings." *Id.* As the Court observed, when relators have been allowed to pursue state law claims based on an alleged nationwide scheme, the complaints have included specific facts around the country to support the scheme. *Id.* at 113. Generalized allegations do not suffice, nor are isolated examples from a small number of locations sufficient to support state law claims across the country. *Id.* at 113–14.

Relator's state FCA claims should be dismissed for the same reasons as the federal claims. In addition, Relator's state law claims fail because Relator has failed to plead sufficient facts to support any state FCA claim. For each state, Relator cites the relevant statutes, but it is well-established that a relator may not state a claim simply by reciting the law and making conclusory assertions regarding how its elements are met.[10] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555

[10] In addition to the citation to the state FCA statutes, Relator cites several state statutes requiring prescribers to obtain preauthorization for patients, including in California, Delaware, Florida,

(2007) ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."). Relator also provides state-by-state listings of Medicaid funds allegedly spent on Betaseron, Nexavar, Stivarga, and Adempas, *see* SAC ¶¶ 282, 284, 286, 288, but showing that a drug was prescribed, used, or paid for in a particular state is not evidence of false claims. These conclusory and generalized references to states should be ignored in the Rule 9(b) analysis.

For most plaintiff states, Relator offers no substance to try to meet the requirements of Rule 9(b) other than the broad and conclusory assertions mentioned above. For example:

- For thirteen listed plaintiffs—Delaware, District of Columbia, Georgia, Hawaii, Indiana, Louisiana, Maryland, Nevada, New Hampshire, New Mexico, Oklahoma, Rhode Island, and Vermont—Relator makes no state-specific allegations in the Second Amended Complaint and attachments.
- For five more—Colorado, Michigan, Montana, Tennessee, and Washington—Relator's only state-specific allegations are to identify one or two employees of the defendants who allegedly worked in the listed state, see SAC ¶¶ 144 & 240 (Colorado), 240 (Michigan), 83 & 126 (Montana), 83 (Tennessee), 83 & 126 (Washington).
- For Connecticut, Iowa and Massachusetts, Relator merely alleges that Medicaid payments were made. SAC ¶¶ 290 (Connecticut), 293 (Iowa), & SAC Ex. K (Massachusetts).
- For Florida, Relator identifies one Bayer employee in the state and alleges the existence of Medicaid payments. SAC ¶¶ 240, 291.

Georgia, Louisiana, Massachusetts, Michigan, Minnesota, New York, North Carolina, Tennessee, and Texas. *See* SAC ¶ 204. These general recitations of state statutory provisions are insufficient to state a claim, and should be ignored for purposes of analyzing whether Relator has stated its claims with the particularity required by Rule 9(b).

- For California and Virginia, Relator identifies one Lash employee in each and alleges the existence of Medicaid payments. SAC ¶¶ 83, 126, & SAC Ex. K (California); ¶ 83 & SAC Exs. E, F, & I (Virginia).
- For Illinois and New York, Relator identifies two Bayer employees in each state and alleges the existence of Medicaid payments. SAC ¶¶ 83, 240 & 292 (Illinois), 83, 240 & SAC Exs. E & F (New York).
- For North Carolina, Relator identifies one employee each for Lash and Bayer, and alleges the existence of Medicaid payments. SAC ¶¶ 83, 240 & 295.

Merely alleging name(s) of employee(s) working in a state, or the fact that Medicaid payments were made for a prescription in that state cannot possibly be sufficient to satisfy Rule 9(b).

For the remaining three states—Minnesota,[11] New Jersey,[12] and Texas[13]—Relator alleges a little more, but even then, Relator's allegations are thin and fail to state a claim. Relator's state-specific allegations largely consist of innocuous facts that do not support any inference of fraud. As shown with the arguments above regarding the federal FCA claims, Relator has failed to allege sufficient particularized facts to meet Rule 9(b), even when considering Relator's nationwide allegations as a whole. When those allegations are parsed to determine whether Relator's claims survive for any particular state, they are even more deficient. Thus, this Court should dismiss all of Relators' state FCA claims for failure to meet the requirements of Rule 9(b).

[11] Relator's Minnesota-based allegations may be found at SAC ¶¶ 84, 114–20, 122–23, 127, 130, 171–73, 204, 226, & 228, & SAC Exs. A & B.

[12] Relator's New Jersey-based allegations may be found at SAC ¶¶ 21, 84, 124–25, 131–37, 168, & 294, & SAC Exs. A, B, D, E, F, H, I, J, & K.

[13] Relator's Texas-based allegations may be found at SAC ¶¶ 65–66, 84, 127, 130, 204, 211, 240, & 296, & SAC Exs. A, B, C, E, F, G, & I.

IV. The Court Should Dismiss Relator's Claims With Prejudice.

Because Relator has had three attempts to plead its claims, and still fails to satisfy Rule 9(b), the Court should dismiss with prejudice. *See* R&R at 7–8 ("When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend under Rule 15(a) before dismissing with prejudice."); *see also U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 761 (S.D. Tex. 2010) (citing *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."). The plain pleading deficiencies demonstrate that Relator cannot meet Rule 9(b)'s requirements. Dismissal with prejudice is also warranted because Relator's SAC demonstrates that any further amendment would be futile. The allegations in the SAC are based largely on Defendants' discovery and misleading interviews with Defendants' unwitting former employees. These improper tactics underscore that Relator lacks any information of its own that it could use to satsify Rule 9(b).

Improper Use of Information Gained Through Discovery: Relator impermissibly uses Defendants' innocuous discovery to give the impression that Relator has sufficient information to meet the requirements of 9(b). *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004) ("[t]he reluctance of courts to permit qui tam relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file a suit as a 'pretext to uncover unknown wrongs'"), *abrogated in part on other grounds by Allison Engine Co.* v. *U.S. ex rel. Sanders*, 553 U.S. 662 (2008). Thirty-five paragraphs in the SAC explicitly quote or refer to specific documents

from Defendants' productions,[14] and at least another 35 paragraphs reference or rely on material produced by Defendants.[15] Relator's use of these materials and its misplaced effort to spin them as evidence of illegality further demonstrate its inability to satisfy Rule 9(b) and serve as grounds for dismissing the SAC with prejudice.

Using discovery to bolster a claim of fraud is inconsistent with the purposes of Rule 9(b) and the FCA. Rule 9(b) would be eviscerated if Relator is allowed to amend its insufficiently-pled complaint with non-public discovery. Consistent with the purposes of Rule 9(b), courts in the Fifth Circuit may prohibit the use of information obtained during discovery to support a claim of fraud. *See Grubbs*, 565 F.3d at 191 ("Rule 9(b) . . . prevents nuisance suits and the filing of baseless claims as a pretext to gain access to a 'fishing expedition.'"). District courts in the Fifth Circuit have held that parties cannot use information obtained in discovery to meet Rule 9(b)'s pleading requirements. *See In re Gulf States Long Term Acute Care of Covington, L.L.C.*, CIV.A. No. 11-1659, 2014 WL 107870, at *2 (E.D. La. Jan. 9, 2014) ("the law in the Fifth Circuit is clear that 'the who, what, when, and were [of a fraud] claim must be laid out *before* access to the discovery process is granted'" (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997))); *U.S. ex rel. Siemens Bldg. Techs., Inc. v. Grot, Inc.*, No. 4:05CV77, 2005 WL 2012263, at *2 (E.D. Tex. Aug. 19, 2005) ("Assuming that Grot is, at this point, able to plead the what, when, where, how, and to whom necessary to sustain its counterclaims, it would clearly be a result of the discovery process."). And courts have dismissed amended FCA complaints when, as here, they rely on information obtained through discovery. *See, e.g., United States State of Fla. ex rel.*

[14] *See* ¶¶ 92, 104–08, 112, 143, 146–49, 150, 152, 161–63, 185, 193, 196, 199, 216–19, 233–34, 240–41, 252–53, 262–63, 278, 301; *see also* Ex. A.

[15] *See* ¶¶ 82, 85, 93, 109, 141–42, 144–45, 151, 155, 160, 164, 167, 195, 197–98, 220, 232, 235–39, 261, 275–78, 298–300, 302, 317–18, 333.

Bingham v. HCA, Inc., No. 13-23671-Civ-COOKE, 2016 WL 6027115, at *5 (S.D. Fl. Oct. 14, 2016) (disregarding relator's FCA allegations based on defendant's discovery and dismissing the amended complaint with prejudice).

Absent Defendants' discovery materials, the SAC is indecipherable from the FAC except for a handful of paragraphs containing allegations based on statements from three previously undisclosed witnesses and irrelevant, unproduced claims data.[16] For example, without quotations and pricing information from Defendants' contracts[17] and reproductions of Defendants' internal presentations,[18] all of which come from Defendants' document productions, Relator has no new allegations regarding the "what," "how," or "when" of the alleged programs. Without Defendants' initial disclosures and document productions, which Relator used to create charts containing the names of Bayer and Lash employees, who they do not even allege were connected to the alleged *quid pro quo* AKS violations, Relator has no new allegations involving the "who" of the alleged schemes. Because Relator cannot use information learned exclusively through discovery to amend its complaint, the Court should disregard these allegations.

Relator's Investigatory Conduct: Relator HCG is "an affiliate" of a non-party New Jersey "research organization" called National Healthcare Analysis Group ("NHAG"), which is responsible for the two similar cases filed in this Court.[19] Relator and its representatives claim to

[16] Relator asserts that as part of its "investigation" it examined "numerous documents concerning the planning, implementation, and execution of the three schemes," SAC ¶ 82, but the documents relied on in the SAC make clear that this element of Relator's "investigation" merely consisted of reviewing Defendants' discovery productions. The specific documents quoted or referenced in the SAC are identified by Bates number in Exhibit A for the Court's reference.

[17] *See, e.g.*, SAC ¶¶ 104–05, 107–08, 146, 148, 150, 161–63, 196, 216–19, 233–34, 252, 333.

[18] *See, e.g.*, SAC ¶¶ 112, 152, 185, 193, 199, 241, 262, 278, 301.

[19] *Health Choice Advocates, LLC v. Gilead Sciences, Inc.*, No. 17-cv-00121-RWS-CMC (E.D. Tex. 2017); *Health Choice Alliance, LLC v. Eli Lilly & Co., Inc.*, 17-cv-00123-RWS-CMC (E.D. Tex. 2017).

have conducted a "rigorous, multi-part investigation" that included "interviews of numerous individuals with knowledge of and involvement in the schemes." SAC ¶ 82. The context surrounding Relator's "investigation" is vital for the Court to understand because the soundbites taken out of context from misleading interviews of former employees form the core of Relator's claims that Defendants have violated the AKS.

Defendants received transcripts of some interviews, *see* Exs. B–L, many of which were conducted by Joseph Locastro, Relator's employee who appears to be a licensed attorney in the state of Pennsylvania.[20] At the time the interviews were conducted, it was already a matter of public record that the organization for which he worked, the National Healthcare Analysis Group, was created for the purpose of pursuing False Claims Act *qui tam* litigation.[21] Yet, during the course of these interviews, Mr. Locastro failed to disclose that (1) he is an attorney; (2) he was collecting information for potential use in a lawsuit; or (3) the organization for which he worked was created to pursue False Claims Act cases. Instead, Mr. Locastro told interviewees that he was "conducting paid market research to judge the effectiveness of the pharmaceutical industry." Exs. B–L. He also told each interviewee that (1) NHAG had "no bias one way or the other about the [healthcare] industry"; (2) his research was to determine whether nurse educators are "an effective and efficient use of resources"; and (3) NHAG hoped "to have a positive influence on how nurse educators are used by pharmaceutical companies." *See, e.g.*, Ex. C–1 at 1.

[20] In the Fifth Circuit, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000) (internal quotations omitted). Here, the transcripts of the confidential interviews are essential to the SAC because Relator's allegations are based upon statements allegedly made by the interviewees.

[21] *See* J.C. Herz, *Medicare Scammers Steal $60 Billion a Year. This Man Is Hunting Them*, Wired (March 7, 2016), https://www.wired.com/2016/03/john-mininno-medicare/.

Additionally, the interview transcripts show that Relator promised interviewees payment for their information. *See* Exs. B–L. On at least one occasion, an interviewee was promised additional compensation if she provided Relator with Defendants' internal company documents, even *after* being told the documents were confidential:

> **Interviewer**: Ok. And actually my last question here is: are you able to share any of your training materials and or procedures or documents? Do you have any of that stuff left from when you were with the Lash Group?
> **CI-4**: Not that I know of, but from what I do understand we are not supposed to share any of that information that has to do with the strict procedures. I don't believe I have any of that information. If I do it's in the back of my closet somewhere.
> **Interviewer**: I know they've compensated people just for them. If you are able to come across of your old stuff. I mean you don't work there anymore so that's why they ask because they didn't want to put you if you are still there in . . . you know what I mean.[22]

Despite Relator's misleading investigatory tactics, not a single interviewee expressed the belief that Defendants' programs were inappropriate or illegal, or that Defendants had an intent to, or were, violating the AKS. Moreover, no interviewee suggested that his or her work caused the submission of a false claim. Instead, many of the interviewees stated that Defendants' programs patients improved patient care.[23]

Ultimately, Relator's third attempt to plead this case is built on little more than Defendants' discovery material and unwitting statements made during a misleading investigation. For these reasons, the Court should dismiss Relator's claims with prejudice.

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[22] Ex. E at 19.

[23] *See* Ex. C–1 at 17 ("It's changed the entire section of patient care for the people who are doing injectables too. In a good way. It's made a wonderful impact for patients."); Ex. F–1 at 10 ("So, the combination that a nurse educator brings to the table is not just the clinical knowledge and expertise but also the patient's emotionally, physically, mentally well-being and it's because of that relationship in that kind of crossover that nurses are usually one of the first people to know when something maybe wrong or be able to predict something that might be coming down the road because of the whole patient not just the clinical.").

CONCLUSION

For the forgoing reasons, Defendants request that the Court dismiss with prejudice Relator's claims.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 3rd day of October, 2018.

/s/ *Claire A. Henry*

CERTIFICATE OF AUTHORIZATION TO FILE UNDER SEAL

This is to certify that the above document should be filed under seal because it contains material designated by the parties as confidential pursuant to the Stipulated Protective Order entered in this case (Dkt. 88).

/s/ *Claire A. Henry*